Remarks

Claims 1-18 are pending in the application. Claims 5 and 18 have been canceled without prejudice. In accordance with 37 CFR 1.78, the specification has been amended to include a specific reference to an earlier application from which benefits are being claimed. Claims 1, 2, 9, and 12 have been amended. Support for the claim amendments can be found throughout the application, including the claims as originally filed. Importantly, no new matter has been added to the claims. The amendments to the claims should not be construed to be an acquiescence to any of the rejections. The amendments to the claims are being made solely to expedite the prosecution of the above-identified application. The Applicant reserves the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

Claim Rejections Based on the Judicially-Created Doctrine of Obviousness-Type Double Patenting

Claims 1-11 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6-9, 12-14, 16, 17, 31, 33, and 35 of U.S. Patent No. 6,299,857 ("the '857 patent").

The Applicants respectfully request that the Examiner hold in abeyance all obviousness-type double patenting rejections based on the '857 patent until allowable subject matter is indicated, at which point the Applicants will file a terminal disclaimer if necessary.

Rejection of claims based on 35 U.S.C. § 102(e)

Claims 1-11 stand rejected under 35 U.S.C. § 102(e) based on the Examiner's contention that they are anticipated by Edwards et al. (U.S. Patent No. 5,744,120). The Applicants respectfully disagree with this contention.

A patent claim is invalid under the provisions of 35 U.S.C. § 102 if it is anticipated by a prior art reference. To anticipate a claim, a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. duPont DeNemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304 (CCPA 1978). The single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

To constitute an anticipatory reference, the prior art must contain an enabling disclosure. *Chester v. Miller*, 906 F.2d at 1546 (Fed. Cir. 1990); see also *Titanium Metals Corp. of America v. Banner*, 778 F.2d at 781 (Fed. Cir. 1985); *Scripps Clinic & Research Found v. Genetech, Inc.*, 927 F.2d 1565, 1578 (Fed. Cir. 1991). A reference contains an enabling disclosure if a person of ordinary skill could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself, and thereby the public, in possession of the invention. *In re Donahue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *In re Sheppard*, 339 F.2d 238, 242 (CCPA 1964). When the reference relied on expressly anticipates all of the elements of the claimed invention, the reference is presumed operable. As a consequence, if no operable technique existed to produce the product or perform the process disclosed by the reference, the reference does not enable what it discloses. See *In re Sasse*, 629 F.2d 675, 681 (CCPA 1980).

The Applicants have amended independent claims 1, 9, and 12 to define the targeting moiety as being selected from (i) cells, including muscle cells, macrophages, foam cells, monocytes, polymorphonuclear cells, cellular fragments and analogs thereof, (ii) colony stimulating factors, and platele factor 4, (iii) growth factors, (iv) cytokines, interferons, and tumor necrosis factors, (v) cellular sources of energy for metabollic active plaque formation, (vi) lipids and lipid receptors, and (vii) component of clotting cascades. Edwards et al. only discloses radiopharmaceuticals where the target moiety is cyclo(D-Val-NmeArg-Gly-Asp-Mamb) (see col. 29-31, Examples 1-10, and col. 32-33, under Utility). Other targeting moieties taught, but not enabled by Edwards et al. also do not include those targeting moieties currently claimed: IIb/IIIa receptor antagonists, IIb/IIIa receptor ligands, fibrin binding peptides, leukocyte binding peptides, chemotactic peptides, somatostatin analogs, and selectin binding peptides (see col. 5, ll. 28-32; col. 15, ll. 5-9; and col. 21-22).

Additionally, the mere assertion (i.e., the assertion absent adequate enablement) that a radiopharmaceutical may be prepared with a different targeting moiety does not constitute a disclosure of the those radiopharmaceuticals sufficient to support a rejection under 35 U.S.C. § 102 based on those radiopharmaceuticals. See *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (concluding that the mere naming of a compound in a reference does not constitute a description of the compound). In other words, the Applicants respectfully assert that because Edwards et al. is not adequate to put the public in possession of radiopharmaceuticals with targeting moieties other than cyclo(D-Val-NmeArg-Gly-Asp-Mamb), Edwards et al. may not be relied upon for a rejection under 35 U.S.C. § 102 based on other targeting moieties.

Accordingly, the Applicants respectfully request the withdrawal of the 35 U.S.C. § 102(e) rejection of claims 1-11.

Rejection of claims based on 35 U.S.C. § 103(a)

Claims 12-18 stand rejected under 35 U.S.C. § 103(a) based on the Examiner's contention that they are obvious over Edwards et al. (U.S. Patent No. 5,744,120). The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate the kit of claims 12-18 based on the teachings of Edwards et al. The Applicants respectfully disagree with this contention. The Applicants have amended independent claim 12, from which claims 13-17 depend, to a kit for cardiovascular imaging, comprising a radionuclide associated with a targeting moiety comprising a component of a process involved in plaque formation, wherein the targeting moiety is selected from (i) cells, including muscle cells, macrophages, foam cells, monocytes, polymorphonuclear cells, cellular fragments and analogs thereof, (ii) colony stimulating factors, and platele factor 4, (iii) growth factors, (iv) cytokines, interferons, and tumor necrosis factors, (v) cellular sources of energy for metabollic active plaque formation, (vi) lipids and lipid receptors, and (vii) component of clotting cascades. It would not have been obvious to one of ordinary skill in the art to prepare the cardiovascular imaging agents of amended claims 12-17 because there is no disclosure or teaching in Edwards et al. for a cardiovascular imaging agent comprising the targeting moieties of amended claims 12-17.

Accordingly, the Applicants respectfully request the withdrawal of the 35 U.S.C. § 103(a) rejection of claims 12-17.

Fees

The Applicants believe that no additional fees are due in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any additional required fee to our Deposit Account, **06-1448**.

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned. A marked-up version of the claims follows.

Respectfully submitted,

FOLEY, HOAG LLP

Michael J. DiVerdi

Michael J. DiVerdi, Ph.D.
Agent for Applicants
Registration No. 51,620

Patent Group
FOLEY, HOAG LLP
155 Seaport Boulevard
Boston, MA 02210

Tel: (617)-832-1000

Fax: (617)-832-7000

Date: June 5, 2003